CAPITOL STREET

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Biopharma: Site Neutral for Hospital Drugs & Cell and Gene Model (33) State Selection

Drug EO Priorities Take Shape; Medicaid Cell & Gene Model Participants Announced

Relevant Companies

Our Take & Next Up

CMS marches forward on drug EO priorities in hospital outpatient proposed rules & on the cell and gene access CMMI model (for sickle cell disease). CMS released its proposed 2026 hospital outpatient pay (here). Policy proposals reflect the Trump drug pricing executive order priorities in (a) implementing site neutral for drugs, and (b) conducting a Medicare drug acquisition survey. CMS also (separately) released an announcement on the Cell and Gene Therapy (CGT) Access Model (here). 33 states (and DC) will participate in the Medicaid model with CMS alluding to potentially expanding the model to other therapeutic spaces.

Key Points

HOSPITAL OUTPATIENT DRUG POLICIES

CMS proposes site-neutral payments for drug administration (saves $280 M a year), in a small negative for hospitals. CMS is proposing to pay for drug administration services furnished at off-campus provider-based departments (PBD) at an amount equal to the site-specific PFS payment rate. This is expected to impact payment for hospital administered oncology drugs, including chemotherapies and immunotherapies (MRK, AZN, LLY, PFE, BMY, Others).

In our view, CMS may finalize this site neutral policy for '26 & then leave Congress to benefit from the savings (in the out years, given LSD billion savings over ten). As a reminder (CBO here) has scored this provision and it was in the mix 2023-24. Site neutral savings could be used by lawmakers as a legislative pay for; CMS also seeks broader comments and pricing data from hospitals in a signal that it will pursue future policies. See our hospital outpatient analysis here.

CMS will conduct a Medicare OPPS drugs acquisition cost survey as directed by drug pricing EO (here) for policymaking in 2027. CMS will be conducting a survey by early 2026 on the acquisition costs for each separately payable drug acquired by all hospitals paid under the OPPS. CMS aims to complete the survey in time to inform policymaking in the 2027 OPPS/ASC proposed rule. We note that this survey is a result of

President Trump's executive order on drug prices which directs HHS to conduct a survey on hospital acquisition costs for outpatient drugs. See our EO analysis here.

CMS is proposing to continue additional payments for certain non-opioid treatments for pain relief. Five drugs and six devices are nominated as qualifying non-opioid treatments for pain relief, and CMS proposes these products be paid separately in both the HOPD and ASC settings, starting in 2026. CMS is requesting comments on additional drugs or devices that could qualify as non-opioid pain treatment.

CMS added IceMan (ENOV) to the list, while the others will continue to be covered. The five qualifying drugs are Exparel (PCRX), Omidria (Rayner Surgical), Dextenza (OCUL), Zynrelef (HRTX), and ketorolac tromethamine injection (GLENMARK, Sagent Pharmaceuticals, APLLTD). The six qualifying devices are ON-Q pump (AVNS), SPRINT peripheral nerve stimulator system (SPR Therapeutics), cryo nerve block therapy (ATRC), ambIT electronic infusion pump (AVNS), Iovera system (PCRX), and IceMan (ENOV).

CELL & GENE MODEL

33 states (and DC) will participate in the Cell and Gene Therapy (CGT) Access Model per CMS announcement. The model is voluntary for states and manufacturers. Participating states represent approximately 84% of Medicaid beneficiaries with sickle cell disease as noted by Dr. Oz at the cell & gene therapy roundtable. See our roundtable analysis here. Participating states include (but are not limited to) CA, CO, CT, DE, FL, KY, LA, MD, MS, NJ, NY, NC, OH, OR, PA, SC, TN, TX.

As a reminder, the Cell and Gene Therapy (CGT) Access Model was initially announced in 2023 under Biden CMMI to address the costs of gene therapies. Under the CGT Access Model, CMS negotiates outcomes-based agreements (OBAs) with manufacturers (BLUE, VRTX, CRSP) on behalf of states and also supports financial and clinical outcome measures development, reconciliation of data, and evaluation of results.

The announcement emphasizes optional additional funding for states under the model to ease implementation challenges. CMS will provide additional funding for implementation and milestone funding for completion of research projects. CMS anticipates awards of up to $9.55 M for each state over the 10.5 years of the award, pending federal availability of funds.

CMS floats the potential for future expansion to cover other diseases with high-cost gene & cell therapies. Oncology and rare diseases remain the top areas of gene therapy development in both the overall pipeline. CAR-T cell therapies are in development for lupus, MS, and HIV/AIDS.

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